

1 BLOOD HURST & O'REARDON, LLP
2 TIMOTHY G. BLOOD (149343)
3 LESLIE E. HURST (178432)
4 THOMAS J. O'REARDON II (247952)
5 600 B Street, Suite 1550
6 San Diego, CA 92101
7 Telephone: 619/338-1100
8 619/338-1101 (fax)
9 tblood@bholaw.com
10 lhurst@bholaw.com
11 toreardon@bholaw.com

12 Attorneys for Plaintiff

13 [Additional counsel appear on signature page.]

14

15 UNITED STATES DISTRICT COURT
16 SOUTHERN DISTRICT OF CALIFORNIA

17 DINO RIKOS, On Behalf of Himself, All
18 Others Similarly Situated and the General
19 Public,

20 Plaintiff,

21 v.

22 THE PROCTER & GAMBLE
23 COMPANY,

24 Defendant.

25 Case No.: 10-CV-1974-BEN(CAB)

26 CLASS ACTION

27 FIRST AMENDED CLASS ACTION
28 COMPLAINT FOR:

1. VIOLATIONS OF CONSUMERS
2. LEGAL REMEDIES ACT, CIVIL
CODE §1750, *ET SEQ.*;
2. VIOLATION OF THE UNFAIR
COMPETITION LAW, BUSINESS &
PROFESSIONS CODE §17200, *ET
SEQ.*; and
3. BREACH OF EXPRESS WARRANTY

29 Courtroom: 3, 4th Floor
30 Judge: Honorable Roger T. Benitez
31 Date Filed: September 21, 2010
32 Trial Date: TBD

33 DEMAND FOR JURY TRIAL

34

35

36

37

38

1 Plaintiff Dino Rikos ("plaintiff"), by and through his attorneys, brings this action on
2 behalf of himself, all others similarly situated and the general public against defendant The
3 Procter & Gamble Company ("Procter & Gamble"), and states:

4 **NATURE OF THE ACTION**

5 1. This is a consumer protection class action addressing the advertisements
6 Procter & Gamble makes about its over-the-counter "digestive care" product called Align®.
7 Through its advertising and labeling, Procter & Gamble claims that Align provides "digestive
8 care" by helping to:

9

- **Build and maintain** a healthy digestive system

10 - **Restore** your natural digestive balance

11 - **Protect** against occasional digestive upsets

12 Procter & Gamble claims in its advertising, including the packaging for Align, that these
13 health benefits result because "Only Align Contains Bifantis®, a Unique, Patented Probiotic,"
14 that "**restore[s] your natural balance and bring peace to your digestive system.**" Procter &
15 Gamble has no support for these claims, even though it states that it does, going so far as to
16 claim it has clinical proof. Procter & Gamble's representations are false, misleading and
17 reasonably likely to deceive the public.

18 2. In March 2009, Procter & Gamble began nationally marketing Align.
19 Prominently placed on its product packaging and in its other advertisements, Procter &
20 Gamble stated and continues to state that Align contains the unique and patented probiotic
21 bacteria "Bifantis®." Procter & Gamble advertised and continues to advertise that "Align is
22 different because only Align contains Bifantis, a patented probiotic strain," that "brings peace
23 to your digestive system" and provides a "restored natural balance to your digestive system."
24 For marketing its Align product, Procter & Gamble uses its trademarked phrase "**GREAT**
25 **DIGESTION THROUGH SCIENCE™.**"

26 3. In truth, the ingredient matrix found in Align has never been substantiated,
27 clinically or otherwise, and Procter & Gamble has no legitimate basis to make these claims. In
28 fact, the only purported clinical trial that Procter & Gamble discusses on its website concerns

1 the effects of Bifantis® in treating symptoms of inflammatory bowel disease (“IBS”), rather
2 than the general population, to whom the advertisements are targeted. Even then, the study
3 concludes that “[n]o statistically significant differences between [placebo and Bifantis] groups
4 were observed at any time-point” relating to daily IBS symptom assessments. Results from
5 this Procter & Gamble funded study are not published in a peer-reviewed scientific journal.

6 4. Procter & Gamble conveyed and continues to convey its deceptive claims about
7 Align through a variety of media, including the Internet, in-store sampling, point of sale
8 displays, and on the Align® probiotic supplement’s labels and labeling. These representations
9 appear prominently and conspicuously on every Align container.

10 5. Through this advertising, Procter & Gamble has conveyed one message: Align,
11 with its probiotic bacteria cultures, provides clinically proven digestive health benefits to the
12 general public. Attached as Exhibit 1 is a collection of some of the advertisements and
13 labeling containing the false and deceptive advertising claim.

14 6. Procter & Gamble’s advertising and marketing campaign is designed to cause
15 consumers to buy Align as a result of this deceptive message, and Procter & Gamble has
16 succeeded. Despite being nothing more than a sugared capsule filled with naturally occurring
17 bacteria, a 28-count package of Align retails for approximately \$30. According to Procter &
18 Gamble, even before its nationwide retail launch, Align was the No. 1 gastroenterologist-
19 recommended probiotic supplement.

20 7. Plaintiff brings this action on behalf of himself and other similarly situated
21 consumers in the United States to halt the dissemination of this false and misleading
22 advertising message, correct the false and misleading perception it has created in the minds of
23 consumers, and obtain redress for those who have purchased Align. Plaintiff alleges violations
24 of the California Consumers Legal Remedies Act, California’s Unfair Competition Law, and
25 breach of the express warranty created by its advertising, including its labeling.

26 JURISDICTION AND VENUE

27 8. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The
28 matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000

and is a class action in which members of the Class of plaintiffs are citizens of states different from Procter & Gamble. Further, greater than two-thirds of the Class members reside in states other than the state in which Procter & Gamble is a citizen.

9. Venue is proper in this Court pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to this action occurred in this district and because defendant:

(a) is authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this district through the promotion, marketing, distribution and sale of its products in this district;

(b) does substantial business in this district; and

(c) is subject to personal jurisdiction in this district.

PARTIES

10. Plaintiff is a resident of the state of Illinois. During the Class period, and in this District, plaintiff was exposed to and saw Procter & Gamble's claims by reading the Align label, purchased Align in this District in reliance on these claims, and suffered injury in fact and lost money as a result of the unfair competition described herein.

11. Defendant Procter & Gamble is a global company headquartered in Cincinnati, Ohio with operations in approximately 80 countries. Procter & Gamble is the self-described largest consumer packaged goods company in the world. Procter & Gamble designs, manufactures, markets and sells beauty and grooming, health and well-being, and household care products, including Align. In 2009, Procter & Gamble spent \$7.5 billion on advertising, and had sales exceeding \$76.7 billion.

FACTUAL ALLEGATIONS

12. In March 2009, on the heels of very successful marketing launches of “functional,” “probiotic” products by food industry giants, and following two years of a scripted marketing plan selling Align exclusively through its website, a toll-free number, and doctors specializing in stomach ailments, Procter & Gamble announced the U.S. retail launch of Align. According to Align’s brand manager at Procter & Gamble, “People take vitamins on a regular basis to help keep their bodies in shape. This dietary supplement can help your body,

1 just like a vitamin." The brand manager also stated, "[w]e know consumers with episodic
2 digestive problems are looking for real solutions, and Align is a clinically proven option....
3 Because Align is grounded in real science and meets a real consumer health need, we expect it
4 to become a cornerstone brand in our personal health care portfolio."

5 13. Since the launch, Procter & Gamble has consistently conveyed the message to
6 consumers throughout the United States that Align, with its unique, patented probiotic bacteria
7 Bifantis®, provides probiotic protection and builds and maintains a healthy digestive system.
8 According to Procter & Gamble, the benefits of Align are backed by clinical proof supporting
9 the "patented probiotic strain exclusively found in Align." These claims are not substantiated
10 and are factually baseless.

11 14. The use of bacteria for probiotic use is in its scientific infancy. In fact,
12 scientists have yet to settle on a definition of probiotic. The World Health Organization's
13 definition of probiotics is "Live microorganisms, which, when administered in adequate
14 amounts, confer a health benefit on the host." The National Center for Complementary and
15 Alternative Medicine ("NCCAM"), one of the centers that makes up the National Institutes of
16 Health, adds that probiotics have an ultimate goal of prevention and treatment of disease.

17 15. On its packaging and labeling, Procter & Gamble defines probiotics: "**What**
18 **are probiotics?** Simply put, probiotics are good bacteria essential for many vital body
19 functions, including healthy digestion." On its website, Procter & Gamble provides a
20 substantially similar definition of probiotics: "What Is a Probiotic? Simply put, probiotics are
21 good bacteria that confer a health benefit and are essential for many vital body functions,
22 including healthy digestion."

23 16. Scientists have not yet mapped the tens of thousands of bacteria strains in the
24 human body's intestinal flora, and do not know whether increasing one type of bacteria
25 provides health benefits. It is also not known whether increasing one type of bacteria can
26 prove harmful. The European Food Safety Authority ("EFSA"), established by the European
27 Union to promote food safety and evaluate food claims, reports that "The numbers/proportions
28 of bacterial groups that would constitute a 'balanced/healthy' intestinal flora have not been

1 established. Increasing the number of any groups of bacteria is not in itself considered as
2 beneficial.” EFSA states that:

3 The gastrointestinal tract is populated with a large number of microorganisms
4 and it normally acts as an effective barrier against generalized systemic
5 infections. It is not possible to provide the exact number of bacterial groups
6 that would constitute a beneficial microbiota.

7 17. There is almost no scientific support for the notion that healthy people, such as
8 those targeted by Procter & Gamble, benefit from bacterial supplements, such as the bacteria at
9 issue. If probiotic bacteria do have any health benefits, they must survive the digestive tract in
10 sufficient quantities to achieve the possible benefit. However, there is no consensus on the
11 quantities of probiotics people might need to ingest, or for how long, in order to achieve a
12 probiotic effect, if probiotics have any such effect in healthy people.

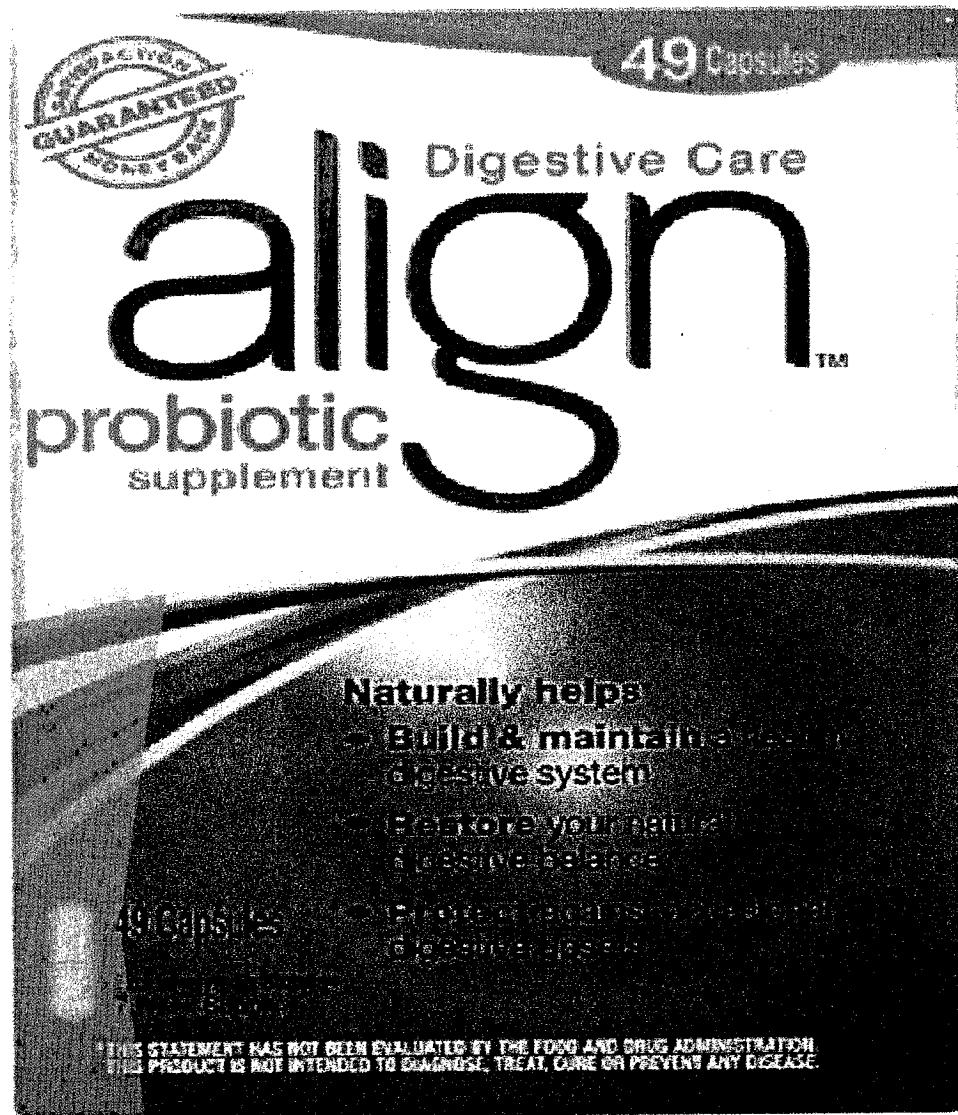
13 18. Using the term as a marketing tool, and without regard to whether it actually
14 delivers any probiotic benefits, Procter & Gamble calls its product “Align® probiotic
15 supplement.” In fact, Procter & Gamble has no legitimate basis to claim that the bacteria with
16 which it laces Align has any beneficial effects when people consume it, that it helps or
17 replaces bacteria naturally found in the human body, that it reduces the growth of “harmful”
18 bacteria, promotes healthy digestion or restores the digestive system.

19 PROCTER & GAMBLE’S CLAIMS ABOUT ALIGN

20 19. Procter & Gamble claims Align, “**Naturally helps: Build & maintain** a health
21 digestive system; **Restore** your natural digestive balance; [and] **Protect** against occasional
22 digestive upsets.” According to Procter & Gamble, “10 years of research went into the
23 formulation of Align®, the only probiotic supplement with patented Bifantis®.”

24 20. Despite inadequate testing, Procter & Gamble states that Align is beneficial for
25 healthy and unhealthy people alike; Align is “for people with healthy digestive function who
26 are looking for help with occasional digestive upsets or who are interesting in promoting their
27 digestive health.”

1 21. Align is described in a medical manner as coming in a "capsule" form. The
2 label on each package of Align substantially appears as follows:



22. On every Align label, Procter & Gamble also prominently claims:

23 **A few words on good bacteria**

24 Your body needs beneficial bacteria for a number of things, including healthy
25 digestion. But they're fragile. Common issues, such as diet, antibiotic use, changes in
26 routine, travel and stress can disrupt your natural balance of good bacteria. Bifantis®,
27

1 only found in Align®, is a probiotic that naturally replenishes your digestive system
2 with healthy bacteria.

3 **Why take Align®?**

4 With just one capsule a day each day, Align helps to build and maintain your digestive
5 health with active probiotic bacteria that support your body's own natural defenses,
6 providing ongoing protection against occasional digestive upsets.

7 **What are probiotics?**

8 Simply put, probiotics are good bacteria essential for many vital body functions,
9 including health digestion.

10 **What makes Align Digestive Care special?**

11 Align contains the patented, pure-strain probiotic bacteria Binfantis® (*Bifidobacterium*
12 *infantis* 35624), which helps naturally balance your digestive system. Bifantis was
13 developed by Gastroenterologists and, when taken daily, will help your body build and
14 maintain a healthy digestive system.

15 Procter & Gamble did not and does not have substantiation for these statements, which are
16 false and misleading and reasonably likely to deceive the average consumer.

17 23. Procter & Gamble deceptively describes Align and Binfantis® on its
18 www.aligngi.com and www.bifantis.com websites. These websites are available to the general
19 public and Procter & Gamble's advertisements in other media promote these websites.
20 Without sufficient testing or substantiation, Procter & Gamble makes the following similar
21 claims on its websites:

22

23

24

25

26

27

28

BLOOD HURST & O'REARDON, LLP

24. On the Align packaging and websites, Procter & Gamble claims that the bacteria culture in Align was developed by doctors and is supported by clinical proof. The Align advertising statements – conspicuously stated on the product label and websites – include:

- Bifantis was developed by Gastroenterologists and, when taken daily, will help your body build and maintain a healthy digestive system.
- **Proof:** Bifantis has been the subject of several clinical studies and has been featured in peer-reviewed journals. Please see Bifantis.com for full details.
- Recommended by Gastroenterologists
- **GREAT DIGESTION THROUGH SCIENCE™**

25. In addition to making untested and unsubstantiated claims, Procter & Gamble's advertising claims that Align has a "Money-Back Guarantee," is likely to deceitfully induce a placebo effect on consumers, irrespective of any actual probiotic effect.

26. On Align packaging, reprinted below, Procter & Gamble states
"SATISFACTION – GUARANTEED – MONEY BACK."

27. On the Align website, Procter & Gamble also promotes the limited “money-back guarantee”:

- Find Digestive Peace ...
or Your Money Back.

- **Peace of Mind at Checkout**

We proudly stand behind the performance of Align® and believe that our patented supplement can help you with your occasional digestive upsets.

28. The front page of the Align website also contains purported testimonials from consumers regarding the benefits of Align:

- *“Align has changed my life. I never thought I’d be able to do the things I love worry-free!”*

The Align website has a page entitled “Align Rating & Reviews” where Procter & Gamble states that “Others have experienced an occasional digestive imbalance and have found Align to be an effective solution.” The Align ratings and testimonials reinforce the deceptive advertising, misrepresenting Align’s ability to combat and ward off digestive system deficiencies. These statements are not adequately supported by the scientific evidence or otherwise substantiated.

SUBSTANTIATION FOR THE CLAIMS DOES NOT EXIST

29. According to a June 2006 report on probiotics published by the American Academy of Microbiology “there is no conclusive evidence that altering the microbiota of a healthy human adult is beneficial.” The report, entitled “Probiotic Microbes: The Scientific Basis,” was prepared by the American Academy of Microbiology, a leadership group of the American Society of Microbiology, which is the leading professional association of microbiologists.

30. Procter & Gamble deceptively conveys the marketing message that Align has been clinically tested and proven. For example, the product labeling states "Clinically proven

1 to naturally defend against 5 signs of digestive imbalance.” And on its website, Procter &
 2 Gamble provides purported scientific information and data, including “clinical publications,”
 3 regarding Bifantis®.

4 31. There are no proper clinical studies that provide substantiation, clinical or
 5 otherwise, for Align’s digestive health claims.

6 32. There is widespread consensus within the legitimate scientific community
 7 concerning the proper research and testing that must be conducted to substantiate a claim made
 8 for a given effect ascribed to a probiotic bacteria. As the American Society for Microbiology
 9 concluded in a symposium focusing on purported probiotic bacteria used in food:

10 There is a pronounced need for large, carefully designed (randomized, placebo
 11 controlled) clinical trials of probiotics that undertake broad sampling of host
 12 microbiota, have clear end points, and have well informed participants who
 13 consent to treatment. Investigations like these are needed to overcome the
 14 placebo effect [of probiotic treatments] and other barriers to the thorough
 15 investigation of probiotic products.¹

16 33. A properly conducted clinical or scientific trial – *e.g.*, one capable of providing
 17 substantiation for Procter & Gamble’s claims – is the well-designed, randomized controlled
 18 trial (“RCT”).² In RCTs, human study subjects similar to each other are randomly assigned to
 19 receive either the test substance or a placebo. Double-blind RCTs, where neither the patient
 20 nor the administering researcher knows which intervention is placebo, is preferred and
 21 considered more accurate than a single-blind RCT. Procter & Gamble has not so much as
 22 attempted to undertake such a process for Align.

23 34. According to a leading group of international scientists and researchers, there
 24 should be a proven correlation in human trials when claiming probiotic health benefits in food
 25 products:

26 ¹ R. Walker & M. Buckley, “Probiotic Microbes: The Scientific Basis,” at 19
 27 (colloquium convened before the American Society of Microbiology, Nov. 5-7, 2005).

28 ² M. Araya, *et al.*, “Guidelines for the Evaluation of Probiotics in Food” (Food and
 29 Agriculture Organization of the United Nations and World Health Organization, Report of a
 30 Joint Working Group, April 30 and May 1, 2002),
http://www.who.int/foodsafety/fs_management/en/probiotic_guidelines.pdf (last visited
 31 August 31, 2010).

The principle outcome of efficacy studies on probiotics should be proven benefits in human trials, such as statistically and biologically significant improvement in condition, symptoms, signs, well-being or quality of life; reduced risk of disease or longer time to next occurrence; or faster recovery from illness. Each should have a proven correlation with the probiotic tested.³

4 35. On its bifantis.com website, Procter & Gamble identifies clinical publications
5 which purportedly substantiate the advertising claims for Align. As explained below, a review
6 of the studies identified by Procter & Gamble demonstrates the falsity of its claims.

7 36. On its website, Procter & Gamble cites to an unpublished purported “clinical
8 trial” involving *B. infantis*, which it funded.⁴ The cited trial involved persons with IBS
9 symptoms, not the general health population to whom Procter & Gamble markets Align.
10 Moreover, the Procter & Gamble trial concluded that the group receiving *B. infantis* did **not**
11 report greater relief in IBS symptoms. That is, the Procter & Gamble trial concluded that “[n]o
12 statistically significant differences between [the control group and *B. infantis* group] were
13 observed at any time-point” relating to daily IBS symptom assessments. Regarding “[w]eekly
14 IBS symptom assessments” the Procter & Gamble trial concluded that “[n]o statistically
15 significant differences were observed between groups during any week except for one
16 parameter at Week 3.” And regarding “[m]icrobiology measures,” the Procter & Gamble trial
17 concluded that “[o]nly 1 measure was statistically different in *B. infantis*-IBS subjects at Week
18 4, Week 8, or Follow-up.”

19 37. On its website, Procter & Gamble cites to two “*Bifidobacterium infantis* 35624
20 Clinical Data Publications.” Neither study provides proof, clinical or otherwise, for the Align
21 claims. The first study (Whorwell, Altringer et al. 2006), looked at women who were primary
22 care IBS patients – not the audience to whom Procter & Gamble markets Align – and tested
23 endpoints that are irrelevant for purposes of providing substantiation for Procter & Gamble’s

25 || 3

⁴ A double-blind, randomized, placebo-controlled study of the effects of Bifantis (*Bifidobacterium infantis* 35624) on fecal microflora and gastrointestinal symptoms in adults with irritable bowel syndrome. P&G Study 2005054. Summary available at <http://www.bifantis.com/probiotic-scientific-data.php#additional> (last visited August 25, 2010).

1 advertising claims. Notwithstanding, the study tested *Bifidobacterium infantis* 35624 at
2 amounts (referred to as “colony-forming units” or “CFUs”) different than what is present in
3 Align® probiotic supplement. The study authors expressly emphasized the variability of
4 results depending on the amount of CFUs: “The lack of benefits observed with the other
5 dosage levels of the probiotic highlight the need for clinical data in the final dosage form.”
6 The second study (O’Mahony, McCarthy, *et al.* 2005) also fails to provide substantiation for
7 the claims. Like the first purported clinical data publication, the second study analyzed
8 persons with IBS, not the population to which Procter & Gamble markets Align. Moreover,
9 the study arm receiving the Align bacteria did not experience any improvement in all bowel
10 movement markers.

11 38. Procter & Gamble’s website also identifies “preclinical data publications” and
12 “review articles” as purported substantiation for the marketing claim made on Align’s
13 packaging and labeling. None provide substantiation for the marketing claim:

- 14 • Debonnet, Garrett, *et al.* 2008: Analyzed potential antidepressant properties of
15 *B. infantis* in rats, and concluded that the “preliminary” findings indicate there
16 is “encouraging evidence” that the probiotic “may possess antidepressant
17 properties.”
- 18 • O’Mahony, Scully, *et al.* 2008: Analyzed cellular interactions in mice infused
19 with *B. infantis* and infected with salmonella.
- 20 • O’Hara, O’Regan, *et al.* 2006: Non-clinical analysis of intestinal cells incubated
21 with *B. infantis*.
- 22 • Sheil, MacSharry, *et al.* 2006: The effects of *B. infantis* consumption on colitis
23 in mice prior to onset of chronic inflammation.
- 24 • O’Mahony, O’Callaghan, *et al.* 2005: In vivo lymph node cell reaction of
25 humans with inflammatory bowel disease undergoing colectomy or small bowel
26 resection to *B. infantis*.

1 • Gilman, Cashman 2006: The effect of *B. infantis* on calcium uptake in human
2 intestinal-like cells in culture. Cells exposed to *B. infantis* did not experience
3 calcium uptake.

4 • McCarthy, O'Mahony, *et al.* 2003: Analyzed *B. infantis*' ability to attenuate
5 colitis in mice.

6 • MacConaill, Butler, *et al.* 2003: Analyzed the molecular biology of the *B.*
7 *infantis* strain.

8 • Brenner, Moeller, *et al.* 2009: Review article concerning randomized controlled
9 trials involving probiotics in the treatment of IBS.

10 • Brenner, Chey, 2009: Review article concerning *B. infantis*' reported effects on
11 IBS symptoms.

12 • Parkes, Brostoff, *et al.* 2008: Review article exploring the role of the gut
13 microbiota in IBS.

14 • O'Sullivan, O'Halloran *et al.* 2005: Generalized review article concerning
15 probiotics, acknowledging that “[k]nowledge of the normal [gut] flora is still
16 relatively meager” and “controlled clinical trials are necessary to validate the
17 benefit of probiotics.”

18 • Dunne, Murphy, *et al.* 1999: Review article concerning the strategy adopted for
19 selection of potentially effective probiotics.

20 39. The studies cited by Procter & Gamble do not constitute clinical substantiation
21 for Align's marketing claims because, *inter alia*, the studies, preclinical or otherwise, involve
22 human and animal disease states, test irrelevant endpoints, and do not analyze *B. infantis* in the
23 quantity and medium delivered in Align.

24 40. Despite inadequate and inapposite testing, Procter & Gamble continues to
25 unequivocally claim that with its proprietary bacterial strain, Align provides digestive system
26 benefits to all persons.

41. Although it is just a tiny, sugared “capsule” of natural bacteria, Align retails for approximately \$30 for a 28-count package.⁵

CLASS ACTION ALLEGATIONS

42. Plaintiff brings this lawsuit on behalf of himself and the proposed Class members under Rule 23(b)(2) and (3) of the Federal Rules of Civil Procedure. The proposed Class consists of:

All persons who purchased Align® until the date notice is disseminated.

Excluded from the Class are defendant's officers, directors and employees and those who purchased Align® for the purpose of resale.

43. Excluded from the Class are the defendant, its officers, directors and employees.

44. *Numerosity.* The members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes, and on that basis alleges, that the proposed Class contains many thousands of members. The precise number of Class members is unknown to plaintiff.

45. *Existence and Predominance of Common Questions of Law and Fact.*
Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether Procter & Gamble had adequate substantiation for its claims prior to making them;

(b) whether the claims discussed above are true, or are misleading, or reasonably likely to deceive;

(c) whether Procter & Gamble's alleged conduct violates public policy;

⁵ See, e.g., <http://www.cvs.com> (\$29.99 for 28-count Align probiotic supplement) (last visited Aug. 30, 2010); <http://www.walmart.com> (\$29.44 for 28-count Align probiotic supplement (last visited Aug. 30, 2010); <http://www.walgreens.com> (\$29.99 for 28-count Align probiotic supplement (last visited Aug. 30, 2010); <http://www.target.com> (\$29.49 for 28-count Align probiotic supplement (last visited Aug. 30, 2010).

(d) whether the alleged conduct constitutes violations of the laws asserted herein;

(e) whether Procter & Gamble engaged in false or misleading advertising;

(f) whether plaintiff and Class members have sustained monetary loss and the proper measure of that loss;

(g) whether plaintiff and Class members are entitled to restitution;

(h) whether plaintiff and Class members are entitled to an award of punitive damages; and

(i) whether plaintiff and Class members are entitled to declaratory and injunctive relief.

46. ***Typicality.*** Plaintiff's claims are typical of the claims of the members of the Class in that plaintiff asserts the same claims.

47. *Adequacy of Representation.* Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel highly experienced in complex consumer class action litigation, and plaintiff intends to prosecute this action vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class.

48. ***Superiority.*** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against the defendant. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done to them.

49. The Class may also be certified because:

(a) the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudication with respect to individual Class members that would establish incompatible standards of conduct for the defendant;

(b) the prosecution of separate actions by individual Class members would create a risk of adjudications with respect to them that would, as a practical matter, be

dispositive of the interests of other Class members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

3 (c) defendant has acted or refused to act on grounds generally applicable to
4 the Class thereby making appropriate final declaratory and/or injunctive relief with respect to
5 the members of the Class as a whole.

6 50. Unless stated otherwise, the claims asserted herein are applicable to all persons
7 who purchased Align.

8 51. Plaintiff seeks preliminary and permanent injunctive and equitable relief on
9 behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and
10 prevent defendant from engaging in the acts described, and requiring defendants to provide full
11 restitution to plaintiff and Class members.

12 52. Unless a class is certified, defendant will retain monies received as a result of
13 its conduct that were taken from plaintiff and proposed Class members. Unless a classwide
14 injunction is issued, defendant will continue to commit the violations alleged, and the
15 members of the Class and the general public will continue to be misled.

16 53. Procter & Gamble has acted and refused to act on grounds generally applicable
17 to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I

**For Violations of the Consumers Legal Remedies Act – Civil
Code §1750 *et seq.* On Behalf of Plaintiff and the Class**

20 54. Plaintiff realleges and incorporates by reference the allegations contained in the
21 paragraphs above as if fully set forth herein.

22 55. This cause of action is brought pursuant to the Consumers Legal Remedies Act,
23 Civil Code §1750, *et seq.* (the “Act”). Plaintiff is a consumer as defined by Civil Code
24 §1761(d). Align is a good within the meaning of the Act.

25 56. Procter & Gamble violated and continues to violate the Act by engaging in the
26 following practices proscribed by §1770(a) of the Act in transactions with plaintiff and the
27 Class which were intended to result in, and did result in, the sale of the Align®:

- (a) Representing that [Align has] . . . characteristics, . . . uses [or] benefits . . . which [it does] not have . . .
- (b) Representing that [Align is] of a particular standard, quality or grade . . . if [it is] of another.
- (c) Advertising goods . . . with intent not to sell them as advertised.
- (d) Representing that [Align has] been supplied in accordance with a previous representation when it has not.

57. Procter & Gamble violated the Act by making the representations described above when it knew, or should have known, that the representations were unsubstantiated, false and misleading.

58. Pursuant to §1782 of the Act, plaintiff Rikos notified Procter & Gamble in writing by certified mail of the particular violations of §1770 of the Act and demanded that Procter & Gamble rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. A copy of the letter is attached hereto as Exhibit 2.

59. Pursuant to §1782(d) of the Act, plaintiff and the Class seek a Court order enjoining the above-described wrongful acts and practices of Procter & Gamble and for restitution and disgorgement.

60. Pursuant to §1782 of the Act, by letter dated September 21, 2010, plaintiff notified Procter & Gamble in writing by certified mail of the particular violations of §1770 of the Act and demanded that Procter & Gamble rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. On September 27, 2010, Procter & Gamble signed the certified mail receipt acknowledging receipt of the letter. A true and correct copy of this letter is attached as Exhibit 2.

61. Procter & Gamble has failed to rectify or agree to rectify the problems associated with the actions detailed above or give notice to all affected consumers within 30 days of the date of written notice pursuant to §1782 of the Act. Therefore, plaintiff further seeks claims for actual, punitive and statutory damages, as appropriate.

62. Procter & Gamble's conduct is malicious, fraudulent and wanton, and provides misleading information that can lead to the delayed treatment of serious and life-threatening illness and diseases.

63. Pursuant to §1780(d) of the Act, attached hereto as Exhibit 3 is the affidavit showing that this action has been commenced in the proper forum.

COUNT II

**Unlawful Business Acts and Practices in Violation of
California Business & Professions Code Section 17200, *et
seq.*, On Behalf of Plaintiff, the General Public and the Class**

64. Plaintiff repeats and realleges the allegations contained in the paragraphs above, as if fully set forth herein.

65. Business & Professions Code §17200 prohibits any “unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.” For the reasons discussed above, Procter & Gamble has violated each of these provisions of Business & Professions Code §17200.

66. Procter & Gamble has violated §17200's prohibition against engaging in unlawful acts and practices by, *inter alia*, making the representations and omissions of material facts, as set forth more fully herein, and violating Civil Code §§1572, 1573, 1709, 1710, 1711, 1770, Business & Professions Code §17200 *et seq.*, Health & Safety Code §110765, 21 U.S.C. §321, 21 U.S.C. §343, by misbranding food, in violation of federal law, and by violating the common law.

67. Plaintiff and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

68. Procter & Gamble's acts, omissions, misrepresentations, practices and non-disclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of Business & Professions Code §17200, *et seq.* in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and

1 unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such
2 conduct.

3 69. As stated in this Complaint, plaintiff alleges violations of consumer protection,
4 unfair competition and truth in advertising laws in California and other states resulting in harm
5 to consumers. Plaintiff asserts violations of the public policy of engaging in false and
6 misleading advertising, unfair competition and deceptive conduct towards consumers. This
7 conduct constitutes violations of the unfair prong of Business & Professions Code §17200, *et*
8 *seq.*

9 70. There were reasonably available alternatives to further Procter & Gamble's
10 legitimate business interests, other than the conduct described herein.

11 71. Procter & Gamble's claims, nondisclosures and misleading statements, as more
12 fully set forth above, were also false, misleading and/or likely to deceive the consuming
13 public within the meaning of Business & Professions Code §17200.

14 72. Procter & Gamble's advertising, including its labeling, as described herein, also
15 constitutes unfair, deceptive, untrue and misleading advertising.

16 73. Procter & Gamble's conduct caused and continues to cause substantial injury to
17 plaintiff and the other Class members. Plaintiff has suffered injury in fact and has lost money
18 as a result of Procter & Gamble's unfair conduct.

19 74. Procter & Gamble has thus engaged in unlawful, unfair and fraudulent business
20 acts and practices and false advertising, entitling plaintiff to judgment and equitable relief
21 against defendants, as set forth in the Prayer for Relief.

22 75. Additionally, pursuant to Business & Professions Code §17203, plaintiff
23 seeks an order requiring Procter & Gamble to immediately cease such acts of unlawful, unfair
24 and fraudulent business practices and requiring Procter & Gamble to engage in a corrective
25 advertising campaign.

26

27

28

1
COUNT III2
Breach of Express Warranty
3
On Behalf of Plaintiff and the Class4
76. Plaintiff realleges and incorporates by reference the allegations contained in the
5 paragraphs above as if fully set forth herein.6
77. Plaintiff, and each member of the Class, formed a contract with defendants at
7 the time plaintiff and the other members of the Class purchased Align. The terms of that
8 contract include the promises and affirmations of fact made by Procter & Gamble on its Align
9 product labels and through other marketing campaigns, as described above. This advertising,
10 including labeling, constitutes express warranties, became part of the basis of the bargain, and
11 is part of a standardized contract between plaintiff and the members of the Class on the one
12 hand, and Procter & Gamble on the other.13
78. All conditions precedent to Procter & Gamble's liability under this contract
14 have been performed by plaintiff and the Class.15
79. Procter & Gamble breached the terms of this contract, including the express
16 warranties, with plaintiff and the Class by not providing the Align product which could
17 provide the benefits described above.18
80. As a result of Procter & Gamble's breach of its contract, plaintiff and the Class
19 have been damaged in the amount of the purchase price of the Align they purchased.20
PRAYER FOR RELIEF21
Wherefore, plaintiff prays for a judgment:22
A. Certifying the Class as requested herein;
23
B. Awarding plaintiff and the proposed Class members damages;
24
C. Awarding restitution and disgorgement of Procter & Gamble's revenues to
25 plaintiff and the proposed Class members;26
D. Awarding declaratory and injunctive relief as permitted by law or equity,
27 including: enjoining defendants from continuing the unlawful practices as set forth herein, and
28 directing defendants to identify victims of its conduct and pay them restitution and

1 disgorgement of all monies acquired by defendants by means of any act or practice declared by
2 this Court to be wrongful;

- E. Awarding plaintiff and the Class damages;
- F. Ordering Procter & Gamble to engage in a corrective advertising campaign;
- G. Awarding attorneys' fees and costs; and
- H. Providing such further relief as may be just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: October 27, 2010

BLOOD HURST & O'REARDON, LLP
TIMOTHY G. BLOOD (149343)
LESLIE E. HURST (178432)
THOMAS J. O'REARDON II (247952)

By: s/Timothy G. Blood
TIMOTHY G. BLOOD

600 B Street, Suite 1550
San Diego, CA 92101
Telephone: 619/338-1100
619/338-1101 (fax)
tbllood@bholaw.com
lhurst@bholaw.com
toreardon@bholaw.com

NICHOLAS & BUTLER, LLP
CRAIG M. NICHOLAS (178444)
ALEX M. TOMASEVIC (245598)
225 Broadway, 19th Floor
San Diego, CA 92101
Telephone: 619/325-0492
619/325-0496 (fax)
cnicholas@nblaw.org
atomasevic@nblaw.org

BONNETT, FAIRBOURN, FRIEDMAN
& BALINT, P.C.
ANDREW S. FRIEDMAN
ELAINE A. RYAN
PATRICIA N. SYVVERSON (203111)
2901 N. Central Avenue, Suite 1000
Phoenix, AZ 85012-3311
Telephone: 602/274-1100
602/798-5860 (fax)
afriedman@bffb.com
eryan@bffb.com
psyverson@bffb.com

Attorneys for Plaintiff

1 CERTIFICATE OF SERVICE
23
4
5
6 I hereby certify that on October 27, 2010, I electronically filed the foregoing with the
Clerk of the Court using the CM/ECF system which will send notification of such filing to the
e-mail addresses denoted on the Electronic Mail Notice List, and I hereby certify that I have
mailed the foregoing document or paper via the United States Postal Service to the non-
ECF/ECF participants indicated on the Electronic Mail Notice List.7 I certify under penalty of perjury under the laws of the United States of America that
8 the foregoing is true and correct. Executed on October 27, 2010.9 s/Timothy G. Blood
1011

TIMOTHY G. BLOOD
1213 BLOOD HURST & O'REARDON, LLP
14 600 B Street, Suite 1550
15 San Diego, CA 92101
16 Telephone: 619/338-1100
17 619/338-1101 (fax)
18 tblood@bholaw.com
19
20
21
22
23
24
25
26
27
28

BLOOD HURST & O'REARDON, LLP